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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	8066-057	6851

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EXAMINER

ASSADI, KATHRYN L

ART UNIT PAPER NUMBER

3763

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/692,123

Applicant(s)

LESCH, PAUL R.

Examiner

Kathryn L Assadi

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: (A) Figures 1-3, (B) Figures 4-6, (C) Figures 7-10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Allan A. Fanucci on April 25, 2002 a provisional election was made without traverse to prosecute the invention of Species (C) Figures 7-10, claims 1-13 and 15. Affirmation of this election must be made by applicant in replying to this Office action. Claim 14 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

OK The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

Claims 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "third stoppers" in Line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "frustroconical shape" in Line 15. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinhardt (US 4,067,333). Reinhardt teaches a medicament cartridge for an injection system comprising, a tube (1), a needle having an injecting end with a bevel (24) and a piercing end with a bevel (23), said piercing end extending into the lumen, a first stopper moveable within the lumen along the longitudinal axis (5), and a second stopper moveable within the lumen along the longitudinal axis (4). Reinhardt teaches that the first stopper has a dimple and narrow cross-section where the needle penetrates the first stopper (Column 3, Lines 18-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhardt in view of van der Wal (US 4,820,286). Reinhardt teaches all of the claimed limitations except an enlarged diameter portion of a lumen and a third stopper within the lumen located between the second stopper and the enlarged diameter and moveable within the lumen along the longitudinal axis. Van der Wal teaches an enlarged diameter portion of a lumen (Column 10, Lines 10-12) and a third stopper (31) within the lumen located between the second stopper and the enlarged diameter and moveable within the lumen along the longitudinal axis (Figure 1). Van der Wal teaches that an enlarged diameter portion of a lumen permits the medicament behind the stopper that is at the enlarged diameter portion to reach the medicament in front of the stopper (Column 8, Lines 1-14). It would be obvious to one with ordinary skill in the art to combine the teachings of Reinhardt and van der Wal in order to create a way for different medicaments to mix with one another. Van der Wal also teaches that addition of a third stopper allows for the addition of another medicament (Column 3, Lines 5-11). It would be obvious to one with ordinary skill in the art to use the teachings of van der Wal to

Art Unit: 3763

modify the invention of Reinhardt in order to add another medicament to the injection device.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhardt in view of Haak (US 5,263,934). Reinhardt teaches all of the claimed limitations except the first stopper having a frustroconical shape and the second stopper having a medicament contacting surface configured and dimensioned to mate with the frustroconical shape of the first stopper to minimize volume of medicament remaining in the lumen after the injection is completed. Haak teaches a first stopper (6) having a frustroconical shape (14) and the second stopper (12) having a medicament contacting surface (13) configured and dimensioned to mate with the frustroconical shape of the first stopper (Figure 1 and Column 2, Lines 53-58). Haak teaches that when the second stopper completely meets with the first stopper, the dead space between the two becomes as small as possible (Column 2, Lines 55-58). It would have been obvious to one with ordinary skill in the art to use the teachings of Haak to modify the invention of Reinhardt in order to create a first stopper having a frustroconical shape and the second stopper having a medicament contacting surface configured and dimensioned to mate with the frustroconical shape of the first stopper to minimize volume of medicament remaining in the lumen after the injection is completed.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhardt in view of Vetter (US 5,139,490). Reinhardt teaches all of the claimed limitations except a medicament containing insoluble particles. Vetter teaches a medicament containing insoluble particles (Column 3, Lines 22-30). It would be obvious

Art Unit: 3763

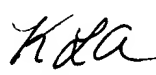
to one with ordinary skill in the art to combine the teachings of Vetter with the invention of Reinhardt in order to be able to use the claimed medicament cartridge with lyophilized medicament.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Assadi whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLA 
May 3, 2002


MICHAEL J. HAYES
PRIMARY EXAMINER